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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
F-5813 (9360-0054.01)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]
on January 2, 2009

Signature Rebecca J. Willis

Typed or printed name Rebecca J. Willis - EV965916569US

Application Number
10/501,571

Filed
4/27/2005

First Named Inventor
Jean-Marie Mathias

Art Unit
3761

Examiner
Philip R. Weist

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 33,723

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

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January 2, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

application of: Jean-Marie Mathias et al.)
)
Serial No: 10/501,571)
)
Filed: April 27, 2005)
)
Art Unit: 3761)
)
Examiner: Philip R. Weist)
)
For: Irreversibly Closable Flow Control Clamp)

Mail Stop AF
Commissioner for Patents
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Name: Rebecca J. Willis

Rebecca J. Willis
Signature

REASONS FOR REVIEW OF FINAL REJECTION

Dear Sir:

In support of the Notice of Appeal and Pre-Appeal Brief Request For Review filed herewith, Applicants are requesting review as set forth below:

Claims 1-13 are pending. Claims 1 and 13 are independent claims. In the Final Office Action of July 3, 2008:

1. claims 1-5, 8-11 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,643,389 to Elson et al
2. claim 6 was rejected under 35 U.S.C. 103(a) as being unpatentable over Elson in view of U.S. Patent No. 6,289,526 to Baumdicker et al.
3. claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Elson in view of U.S. Patent No. 4,193,174 to Stephens.
4. claims 1-5, 8-12 and 13 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,089,527 to Utterberg in view of Elson.

Applicants respectfully submit that there is clear error in the Examiner's rejections in the Final Office Action of July 3, 2008 as set forth below.

Claims 1-5, 8-11 and 13 Would Not Have Been Obvious over U.S. Patent 4,643,389 to Elson

With regard to the rejection of claims 1-5, 8-11 and 13 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,643,389 to Elson et al, Applicants respectfully submit that independent claims 1 and 13 and the respective dependent claims would not have been obvious over the cited '389 patent, and the Office has failed to make a prima facie showing of obviousness to support the rejection under § 103.

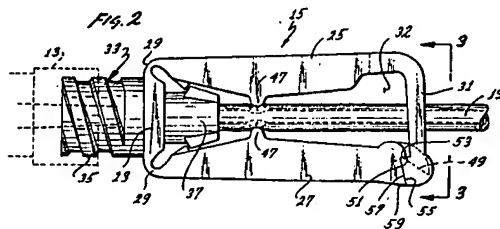
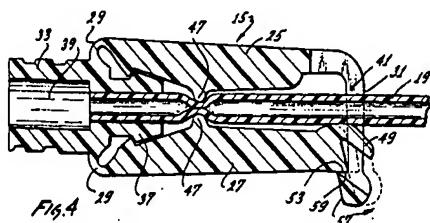
Specifically, independent claim 1 recites a flow control clamp comprising a flexible body having a first leg and a second leg disposed in a general facing relationship when in a first spaced apart position and in a second closed position, the legs being movable from the first position to the second position. Claim 1 further recites a pair of apertures in the body for receiving a flexible tube therethrough and at least one tube contacting member carried by one of the legs for clamping a tube when the legs are in the closed position. The first and second legs are adapted to irreversibly secure the legs together in the second closed position.

Separately, independent claim 13 recites a flow control clamp and tube comprising a flexible body having a first portion and a second portion wherein the first portion and second portion are movable from a first open position to a second closed position. Claim 13 further recites a flexible tube extending between the first and second portions and at least one tube contacting member carried by one of the portions for compressing the tube when the portions are in the second closed position such that fluid flow through the tube is substantially prevented. The first and second portions are adapted to irreversibly maintain the clamp in the second closed position. It will be appreciated that in claim 13, the second closed position is defined by the condition of the tubing within the clamp (i.e. compressed) and flow of fluid through the tube (i.e. substantially prevented).

The clamp recited in independent claims 1 and 13 is not disclosed or even contemplated in Elson. In fact, the exact opposite—a reversibly securable or reopenable clamp—is disclosed in Elson. Specifically, Elson does not disclose first and second legs (or first and second portions as recited in claim 13) including surfaces disposed to irreversibly secure the legs together in a closed position. In fact, the Office specifically acknowledges this fact, and states in the Office Action (page 2) that “Elson...does not specifically disclose that the legs are adapted to irreversibly secure the legs together in the closed position.” Nor does Elson disclose a flow control clamp in which fluid flow through a tube is substantially prevented when first and second portions are irreversibly secured in a closed position compressing a tube, as recited in claim 13.

Indeed, Elson repeatedly emphasizes that body members (arms) 25, 27 are reversibly closable meaning they can easily be moved from a clamping position to a releasing position in which arms 25 and

27 are movable away from each other. In one example, Elson states that “arms [25] and [27] are relatively movable toward each other to a clamping position ...and also relatively movable away from each other to a releasing position in which the clamping members 47 impose essentially no restriction to flow through the tube 19” (emphasis added). See col. 3, lines 48-55.



The clamping and releasing positions of the Elson clamp can also be seen in exemplary Figures 2 and 4, reproduced above. As seen in the Figures, arms 25 and 27 of Elson are movable between a clamping position (in which the clamping members 47 tightly compress the tube 19 to block flow of fluid therethrough (Figure 4) and a releasing position in which fluid can flow through tube 19 (Figure 2)). Once the clamp is in a clamping position, Elson further describes that “to move the arms 25 and 27 back to the releasing position, the physician pushes with his thumb...so that the resilience of the hinge 29 can move the arm 27 back to the releasing position of FIG. 2.” Furthermore, Elson even emphasizes the ease by which this “reversibility”, or capability to repeatedly move between a clamping and a releasing position can be accomplished, such as “[it] can be manually moved between the clamping and releasing positions with only one hand”. See col. 4, lines 32-56. The numerous and explicit references to the reversibility of the Elson clamp stand in stark contrast to the clamp recited in independent claim 1 and even more particularly to independent claim 13 which recites a clamp that is irreversibly closed and cannot easily be reverted from a “no-flow” condition to a “flow” condition.

While Applicants believe that it is abundantly clear from the disclosure of Elson that the clamp disclosed therein is reversible (and desirably so), the Office argues that Elson describes a “positive lock” that holds the clamp shut, allegedly making the clamp of Elson “irreversible.” However, if read closely, the disclosure of Elson relating to a “positive lock” is not a reference to irreversibly locking a clamp in a closed position, or to restrict fluid flow through a tube. Instead, it is simply a reference to the arms being in a facing relationship or “loop” configuration instead of a flat configuration as shown in Elson Figure 6. Even when the clamp is in the “positive lock” or closed loop configuration, the arms still are reversibly closable: “this positive lock is effective when the arms are in either the releasing or clamping positions. See Elson, col. 1, line 68 - col. 2, line 2.

In the Office Action, it has also been argued that it would have been obvious to modify the clamp of Elson with the ability to “permanently lock the clamp in order to prevent the clamp from accidentally

coming unattached from the tubing member during a medical procedure” (emphasis added). This argument, however, misses the point. The pending claims (e.g. claim 13) are directed to a flow control clamp for substantially preventing fluid flow through tubing when in an irreversibly closed position. Whether or not Elson discloses a clamp that is permanently *attached to tubing* is irrelevant because, at the end of the day, it would still be a reversible clamp, movable between open (“flow”) and closed (“no-flow”) positions, contrary to the clamp recited in claims 1 and 13.

Notwithstanding the numerous references in Elson to the reversibility of the clamp described therein, the Office argues that “it would have been obvious ...to omit the [Elson] clamp’s ability to be repeatedly opened and closed if the ability to be reopened was not desired”. However, what structure in the Elson clamp would allow one to omit the reversibility feature? There is no disclosure in Elson of an irreversibly closeable clamp or of a structure that could serve to irreversibly secure the Elson clamp. In addition, why one would want to irreversibly secure the Elson clamp in a closed position when, in fact, Elson touts the exact opposite—a clamp that is reversibly openable and desirably so—is never explained. As expressly described in Elson, the clamp is intended to be re-openable, and needs to be re-openable, to allow air to flow from syringe 13 through tube 19 to inflate balloon 17, which is used to carry portions of catheter 11 to a desired location within a patient during a medical procedure. When the procedure is complete, “the clip 15 is returned to the releasing position of FIG. 2... to allow deflation of the balloon 17”. See Elson, col. 4, lines 42-56. What the Office is suggesting is a modification that changes Elson in a fundamental way (i.e. to omit Elson’s ability to be re-opened), and one that is directly contrary to the way in which the Elson clamp is designed and intended to be used. The proposed modification conflicts directly with the Office’s own guidelines set forth in the MPEP 2143.01 (V), which reads “[i]f the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.” Also see *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984). For at least these reasons, independent claims 1 and 13 and the respective dependent claims 2-5 and 8-11 would not have been obvious over the Elson patent.

Claims 6 and 7 Would Not Have Been Obvious Over Elson In View of Baumdicker and/or Stephens

Next, Applicants turn to the rejection of dependent claims 6 and 7 over Elson in view of the ‘526 patent to Baumdicker and the ‘174 patent to Stephens, respectively. In this regard, Applicants note that claims 6 and 7 are dependent on claim 1. For at least the reasons stated above (which are incorporated herein by reference) claims 6 and 7 also would not have been obvious over Elson, and neither Baumdicker nor Stephens disclose the subject matter missing from Elson. That is, neither Baumdicker nor Stephens describe an irreversible flow control clamp. Thus, dependent claims 6 and 7 would not have been obvious over Elson, either alone or in combination with Baumdicker and/or Stephens.

Claims 1-5, 8-12 and 13 Would Not Have Been Obvious Over Utterberg in view of Elson

Next, Applicants turn to the rejection of claims 1-5, 8-12 and 13 under 35 U.S.C. 103 as being unpatentable over Utterberg (US 6,089,527) in view of Elson. Applicants respectfully submit that independent claims 1 and 13 the respective dependent claims 2-5 and 8-12 would not have been obvious over Utterberg either alone or in combination with Elson.

Specifically, Utterberg does not describe first and second legs (or portions as defined in claim 13) adapted to be irreversibly secured together in a closed position as required by claims 1 and 13. Further, Utterberg does not disclose a flow control clamp in which fluid flow through a tube is substantially prevented when first and second portions are irreversibly secured in a closed position compressing a tube, as required by claim 13. Instead, Utterberg discloses a squeeze clamp for tubing, which (like Elson) is reversible between an open and closed position, and the Office has expressly acknowledged this fact – that is, the Office has indicated that “Utterberg does not disclose that the first and second surfaces are adapted to irreversibly secure the legs together in a closed position”. See Final Office Action, page 5. Thus, even if one were to combine the reversible clamp described by Utterberg with the reversible clamp of Elson, the resulting device would still be a reversible clamp and combining Utterberg with Elson would not cure the deficiencies of Elson and would not result in one arriving at the claimed irreversible flow control clamp.

Conclusion

For at least the above reasons, it is respectfully submitted that independent claims 1 and 13 and the respective dependent claims would not have been obvious over Elson, either alone or in combination with Baumdicker, Stephens and/or Utterberg, and there is clear error in the Examiner’s rejections in the Final Office Action of July 3, 2008. Accordingly, the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

Date: January 2, 2009

By: 

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